

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**IN RE: FRESENIUS
GRANUFLO/NATURALYTE
DIALYSATE PRODUCTS LIABILITY
LITIGATION**

MDL NO.: 1:13-MD-2428-DPW

This Document Relates to:

FILED UNDER SEAL
LEAVE TO FILE GRANTED ON
10/12/2017

Charles Cameron, Individually and as Wrongful
Death Beneficiary of Charles Cameron, Sr.,
Cause No. 1:13-cv-12446

Daniel Carter, Individually and as Wrongful
Death Beneficiary of Anniece Carter,
Cause No. 1:13-cv-12459

Sophia Walker, Individually and as Wrongful
Death Beneficiary of Hattie Myles,
Cause No. 1:13-cv-12487

REDACTED

**RESPONSE IN OPPOSITION TO MOTION FOR SUMMARY JUDGMENT ON THE
CLAIMS OF OPT-OUT CASES INVOLVING NATURALYTE**

FILED UNDER SEAL
LEAVE TO FILE GRANTED ON 10/12/2017

NOW INTO COURT, through undersigned counsel, come the above-referenced Plaintiffs, who file their Response in Opposition to Motion for Summary Judgment on the Claims of Opt-Out Involving NaturaLyte and would show unto the Court the following:

There are genuine issues of material fact regarding claims involving Naturalyte, and questions of fact are properly the province of a jury. The motion for summary judgment should be denied.

STANDARD FOR SUMMARY JUDGMENT

The standard for summary judgment is well-known. Summary judgment is appropriate only if there are no genuine issues of material fact and movant is entitled to judgment as a matter of law. Fed. R. Civ. Pro. 56. *Cross v. Cummins Engine Co.*, 993 F.2d 112 (5th Cir. 1993). Disputes over facts that might legitimately affect the outcome are material and, in applying the test, the court must view the evidence in the light most favorable to the nonmovant. *Anderson v. Liberty Lobby*, 477 U.S. 242 (1986).

BURDEN OF PROOF

At this stage in the litigation, absent case-specific discovery, to prove general causation, Plaintiffs must proffer evidence that the product at issue is **capable** of causing their alleged injuries. *In Re Norplant Contraceptive Prods. Liab. Litig.*, 215 F.Supp. 2d 795, 830 (E.D. Tex. 2002)(emphasis added); *In Re Mirena IUD Prods. Liab. Litig.*, 202 F.Supp. 3d 304, 310 (S.D.N.Y. 2016). Generally, Plaintiff must then also proffer evidence that the product did, in fact, cause the injury in each individual case - i.e., specific causation. *Id.*

GENERAL CAUSATION EVIDENCE REGARDING NATURALYTE

The Fresenius Defendants have filed this Motion for Summary Judgment on the basis that

NaturaLyte was used in the dialysis treatment of Plaintiff's Decedent [REDACTED]. Fresenius admits that records are insufficient to establish that Decedents

[REDACTED] were dialyzed with GranuFlo, rather than NaturaLyte.

Plaintiffs respectfully submits that the Motion for Summary Judgment is without merit.

Plaintiffs have proffered numerous experts who have opined that NaturaLyte can cause the injuries alleged in Plaintiffs' Complaints, and can establish general causation evidence sufficient to survive dismissal in a summary judgment posture.

**PLAINTIFFS HAVE PROFFERED EVIDENCE TO SUPPORT A CLAIM THAT
NATURALYTE SUBSTANTIALLY CONTRIBUTED TO THE INJURIES ALLEGED**

Evidence in this case has clearly established that there are risks associated with giving dialysis patients too much bicarbonate¹. Plaintiffs' case is based on the premise that Fresenius' failure to warn and instruct regarding these risks rendered its product unsafe and defective, and substantially contributed to Plaintiffs' Decedent's deaths.

The safety of NaturaLyte as a dialysate component, just as with GranuFlo, depends on its proper use, which in turn requires adequate warnings and instructions. There is overwhelming evidence that both NaturaLyte and GranuFlo were distributed and sold for use in an environment of widespread confusion - about which Fresenius knew, and which Fresenius caused - concerning the proper and safe use of NaturaLyte and GranuFlo as they relate to total buffer delivered to dialysis patients, including the Decedents herein. This confusion was evident and documented repeatedly.²

¹See Exhibit 1: Plaintiffs' Omnibus Memorandum in Support of Causation, incorporated by reference as if fully re-stated herein.

²Examples attached as Exhibit

NaturaLyte is dangerously defective because of Fresenius' failure to adequately warn and instruct its Medical Directors, nurses, technicians and nephrologists, or any other medical personnel not employed by Fresenius Defendants, as to safe recommended amounts of bicarbonate for dialysis of the entire population, including Decedents herein.

EXPERT OPINION EVIDENCE THAT NATURALYTE IS CAPABLE OF CAUSING THE INJURY

The Plaintiffs' theory of the case includes the premise that as a result of conversion of acetate into bicarbonate, a patient's serum bicarbonate levels increase, thereby exposing the dialysis patient to a greater amount of serum bicarbonate than the patient's physician anticipated when prescribing the bicarbonate concentrate. This can result in metabolic alkalosis, which, in turn, increases the risk of arrhythmia, cardiopulmonary arrest, and sudden cardiac death. The sum of bicarbonate the patient receives from the bicarbonate concentrate and from the acetate conversion is referred to as "total buffer." In these cases, when a patient's doctor prescribed the amount of bicarbonate concentrate for the dialysate, the doctor prescribed either NaturaLyte or GranuFlo. NaturaLyte contains 4 milliequivalents per liter ("mEq/L) of acetate; GranuFlo contains 8 mEq/L of acetate. The liver converts the acetate into bicarbonate. Plaintiffs allege that Fresenius should have warned physicians to be aware of total buffer when prescribing the bicarbonate concentrate.

During the course of this litigation, Dr. Steven C. Borkan, a nephrologist whom the Plaintiffs have named as an expert in general causation, states that “_____”

[REDACTED]

[REDACTED]

[REDACTED]³ Fresenius has previously argued should not be permitted to testify that 4 mEq/L of acetate is “excess” given that he had previously testified in the context of other litigation that 4 mEq/L is acceptable, and that patients at his own clinic are treated with an acid concentrate containing 4 mEq/L of acetate. This Court previously held that any criticism Fresenius had of Dr. Borkan’s opinion **concerns its weight, not its admissibility**. It is a Court’s duty to determine the legal principles applicable to a case, but it is the jury’s exclusive province to apply the law to the facts of the case. *United States v. Johnson*, 718 F.2d 1317 (5th Cir. 1983). At his deposition, Dr. Borkan defined [REDACTED] [REDACTED].” Throughout his report, Dr. Borkan references various journal articles as support for his opinion that [REDACTED] [REDACTED]”. In his report, Dr. Borkan opined that Fresenius [REDACTED] [REDACTED] [REDACTED] Fresenius sought to preclude Dr. Borkan from expressing this opinion but the motion to preclude was DENIED⁴.

Dr. Julian M. Aroesty, a cardiologist designated as an expert in the case, opines that the

“[REDACTED]
[REDACTED]
[REDACTED]....[REDACTED]

³Dr. Borkan Report at 22, attached hereto as Exhibit 3.

⁴Id.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]⁵ (emphasis added)

Dr. Joseph Akar, a cardiologist designated as an expert for the Plaintiffs, opined in his report that patients with End Stage Renal Disease on hemodialysis are [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]⁶ (emphasis added) Dr. Akar's opinions regarding the types of injuries that could be cause by GranuFlo and NaturaLyte create a genuine issue of material fact that precludes summary judgment.

Dr. Lucius Lampton submitted expert reports for each of the Decedents which state that, to a reasonable degree of medical certainty, the use of NaturaLyte proximately caused Decedent's death.⁷

MASSACHUSETTS JURY VS. MISSISSIPPI JURY

This Court previously denied a substantially similar motion for summary judgment by Fresenius in the *Dial* litigation (Cause No. 1:14-cv-11101). In *Dial*, Fresenius argued that summary judgment was appropriate because Plaintiff's Decedent Carley Dial received that

⁵Exhibit 5: Aroesty Report at 18.

⁶Exhibit 6: Dr. Akar's Expert Report at 15.

⁷Exhibit 7: Lampton Reports

Fresenius-manufactured acid concentrate NaturaLyte, which contains 4 mEq/L of acetate.⁸ In the *Dial* case and in its' argument in support of summary judgment herein, Fresenius claims that NaturaLyte does not contain the 4 extra mEq/L of acetate that plaintiffs claim renders GranuFlo unsafe without additional warning. The evidence shows, however, that the risks associated with giving too much bicarbonate to dialysis patients involves both GranuFlo and NaturaLyte, as evidenced by Defendants' own studies.⁹

Based on testimony given in the *Dial* trial, Fresenius seems to be arguing that because a Massachusetts jury found that there was insufficient causation evidence, a Mississippi jury would do the same. It will not surprise the Court that Plaintiffs do not believe that a Mississippi jury would automatically reach the same conclusion as a Massachusetts jury. The issue of general causation regarding NaturaLyte is a question of fact, for a finder of fact, and summary judgment should be denied.

CONCLUSION AS TO GENERAL CAUSATION

For all of the aforementioned reasons, general causation as to whether NaturaLyte is capable of causing the injury cannot be credibly contested. Considering the totality and the weight of the evidence, particularly when viewing the evidence in the light most favorable to the non-movant, the Court should deny summary judgment.

E. In the Alternative, Plaintiffs Request Additional Time Pursuant to Rule 56(d)

In the alternative, Plaintiffs request additional time pursuant to Rule 56 (d) to respond to

⁸As compared to GranuFlo, which contains 8mEq/l of acetate.

⁹ See Exhibit 2: *Dial* Response in Opposition to Motion for Summary Judgment, incorporated by reference as if fully re-stated herein.

the Motion for Summary Judgment On Claims of Opt-Out Cases [REDACTED]

[REDACTED]¹⁰

This the 16th day of October, 2017.

Respectfully submitted,

s/Dunbar Watt
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CERTIFICATE OF SERVICE

I hereby certify that on this the 16th day of October, 2017, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system, which will send notice of electronic filing to all counsel of record. I further certify that I mailed the foregoing document and the notice of electronic filing by first-class mail to those who are non-CM/ECF participants.

s/Dunbar Watt
Dunbar Watt, Esq.
Attorney for Plaintiffs

¹⁰The Affidavit of Dunbar Watt is attached hereto detailing specific reasons why case-specific discovery is warranted.

